



TOXICOLOGY DEPARTMENT
P.O. BOX 12014, 2 T.W. ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, N.C. 27709
(919) 549-2000 TELEFAX (919) 549-2925
INTERNATIONAL TELEX NUMBER 4999378 - ANSWERBACK APC RTP

ORIGINAL

Contains No CBI

September 1, 1994

(A)



8EHQ-94-13265
INIT 09/12/94

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
P 640 082 526

OPPT Document Processing Center (7407)
ATTN: Section 8(e) Coordinator
Office of Pollution Prevention and Toxics (OPPT)
US Environmental Protection Agency
Washington, DC 20460



88948888368

RECEIVED
OPPT CDIC
94 SEP 12 AM 8:02

RE: TSCA Section 8(e) Notice

Dear Sir or Madam:

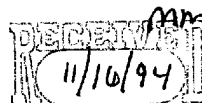
CAS # 39807-15-3

This notice is being submitted by Rhône-Poulenc Ag Company (RPAC) to the Environmental Protection Agency (EPA) in accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), 15 USC § 2607 (e).

We are submitting results from two toxicity studies in rats with RP 020630 [chemical name 5-tert-butyl-3-(2,4-dichloro-5-propargyloxyphenyl)-1,3,4-oxadiazol-2-(3H)-one]. This compound is being studied for research and development purposes.

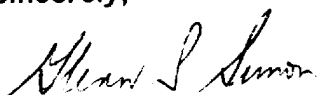
✓ No claims of confidentiality are made for this submission.

In a preliminary developmental toxicity study in rats, RP 020630 was administered at 0, 50, 100, 500, and 1000 mg/kg/day (10 females/group) on gestation days 6 through 15 inclusive. The only evidence of maternal toxicity was lower weight gains at 500 and 1000 mg/kg/day between gestation days 15 through 20. Cesarean sectioning data showed statistically significant decreases in the mean number of live fetuses per litter at 100, 500, and 1000 mg/kg/day, statistically significant increases in the mean number of late resorptions per litter and percent post-implantation loss at 500 and 1000 mg/kg/day, statistically significant decreases in mean fetal weights at 50, 500, and 1000 mg/kg/day, and statistically significant decreases in mean placental weights at 500 and 1000 mg/kg/day. A number of edematous fetuses were noted at 1000 mg/kg/day. Increased fetal incidences of incomplete ossification were noted at 500 and 1000 mg/kg/day for various bones in the head (interparietal, nasal, frontal, parietal, occipital, maxillary, premaxillary, mandibular, jugal squamosal, tympanal), first, second, third, and fourth sternebrae, all lumbar and sacral vertebrae, pubic bones, and fifth metatarsus. In addition, increased fetal incidence of less than five caudal vertebrae and wavy or bent ribs were observed at 500 and 1000 mg/kg/day. Based on an assessment of other developmental toxicity studies conducted at the laboratory, RPAC believes the validity of some of the findings in this study are subject to question.



Further questions regarding this submission may be directed to the undersigned at 919-549-2222.

Sincerely,

A handwritten signature in cursive script, appearing to read "Glenn S. Simon".

Glenn S. Simon, PhD, DABT
Director of Toxicology



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Glenn S. Simon, Ph.D., DABT
Director of Toxicology
Rhône-Poulenc
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAR 15 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

13205A



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contains at least 50% recycled fiber

Triage of 8(e) Submissions

Date sent to triage: AUG 22 1985

NON-CAP

CAP

Submission number: 13205A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.):

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: 0 1 2 pages 1,2 pages 1,2

Notes:

Contractor reviewer:

PJR

Date:

12/7/94

CECATS DATA
Submission # BEHO-0994-13205 SEQ. A

TYPE INT SUPP FLWP

SUBMITTER NAME: Rhone-Poulenc

Ag Company

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL. ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)
DISPOSITION:
0639 REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS
0601 NO ACTION IN PROGRESS
0602 STUDY IN PROGRESS
0603 ACTION IN PROGRESS
0604 LABORATORY (13205)
0605 PROFESSIONAL (13205)
0606 APP USE DISCONTINUED
0607 PRODUCTION DISCONTINUED
0608 CONFIDENTIAL

SUB. DATE: 09/01/94 DATE: 09/12/94 CSRAD DATE: 11/16/94

CHEMICAL NAME:

1,3,4-Oxadiazol-2-(3H)-one, 5-tert-butyl-
3-(2,4-dichloro-5-propoxyphenoxy)-

CASE
39807-15-3

INFORMATION TYPE:		P.F.C.		INFORMATION TYPE:		P.F.C.		INFORMATION TYPE:		P.F.C.				
0201	ONCO (HUMAN)	01	02	04	0216	EPICLIN	01	02	04	0241	IMMUNO (ANIMAL)	01	02	04
0202	ONCO (ANIMAL)	01	02	04	0217	HUMAN EXPOS (PROD CONTAM)	01	02	04	0242	IMMUNO (HUMAN)	01	02	04
0203	CELL TRANS (IN VITRO)	01	02	04	0218	HUMAN EXPOS (ACCIDENTAL)	01	02	04	0243	CHEM/PHYS PROP	01	02	04
0204	MUTA (IN VITRO)	01	02	04	0219	HUMAN EXPOS (MONITORING)	01	02	04	0244	CLASTO (IN VITRO)	01	02	04
0205	MUTA (IN VIVO)	01	02	04	0220	ECOAQUA TOX	01	02	04	0245	CLASTO (ANIMAL)	01	02	04
0206	REPRO/TERATO (HUMAN)	01	02	04	0221	ENV. OCCURRENCE	01	02	04	0246	CLASTO (HUMAN)	01	02	04
0207	REPRO/TERATO (ANIMAL)	01	02	04	0222	EMERG INCI OF ENV CONTAM	01	02	04	0247	DNA DAMAGE/REPAIR	01	02	04
0208	NEURO (HUMAN)	01	02	04	0223	RESPONSE REQUEST DELAY	01	02	04	0248	PRODUSE/PROC	01	02	04
0209	NEURO (ANIMAL)	01	02	04	0224	PRODCOMP/CHEM ID	01	02	04	0251	MSDS	01	02	04
0210	ACUTE TOX. (HUMAN)	01	02	04	0225	REPORTING RATIONALE	01	02	04	0299	OTHER	01	02	04
0211	CHR. TOX. (HUMAN)	01	02	04	0226	CONFIDENTIAL	01	02	04					
0212	ACUTE TOX. (ANIMAL)	01	02	04	0227	ALLERG (HUMAN)	01	02	04					
0213	SUB ACUTE TOX (ANIMAL)	01	02	04	0228	ALLERG (ANIMAL)	01	02	04					
0214	SUB CHRONIC TOX (ANIMAL)	01	02	04	0229	METAB/PHARMACO (ANIMAL)	01	02	04					
0215	CHRONIC TOX (ANIMAL)	01	02	04	0230	METAB/PHARMACO (HUMAN)	01	02	04					

TRIAL DATA: NON-CBI INVENTORY ONGOING REVIEW: SPECIES RAT TOXICOLOGICAL CONCERN: USE: PRODUCTION:

CAS SR NO YES YES (DROP/REFER) NO (CONTINUE)

(IN NAMING)

REFR

MED HIGH

UNCLASSIFIED Non-CBI gases, bioassays

500-1000 mg/kg - red 20 min, see number of lobe morphologies, see placental and, inc. metabolite manufacture (delayed observation), see # of live fetuses, see in fetal autopsies, see number of live fetuses, note: for method 50 mg/kg - see fetal site